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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,189	03/11/2004	Martin B. Wax	P-3023-US2	4962
49443 7590 05/01/2007 PEARL COHEN ZEDEK LATZER, LLP 1500 BROADWAY 12TH FLOOR NEW YORK, NY 10036			EXAMINER O HARA, EILEEN B	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 05/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/797,189

Applicant(s)

WAX ET AL.

Examiner

Eileen B. O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 18-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/11/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 18-24 are pending in the instant application.

Election/Restrictions

2. Applicant's election of method of treatment of glaucoma with a compound or composition which limits the synthesis or release of TNF- α in reply the filed on February 2, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

All claims are currently under examination.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Priority to Application Number 09/500,023 has been claimed under both 35 U.S.C. 119(e) and 35 U.S.C. 120, and it is only entitled to priority under 35 U.S.C. 120.

Specification

4. The disclosure is objected to because of the following informalities: in the legend to Figure 13 on page 9, on the third line is written "TNF-□", which should be changed to "TNF- α ". Also on page 39, line 27, "TNF-□", should be changed to "TNF- α ".

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On page 41, line 24, "16 □g/ml" is written as the amount which should be corrected.

Appropriate correction is required.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on March 11, 2004 has been considered by the examiner.

5.2 The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Priority

6. This application filed under former 37 CFR 1.60 lacks the current status of the nonprovisional parent applications. The patent numbers should be included in the cross-reference to related applications. See 37 CFR 1.78 and MPEP § 201.11.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

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A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7.1 Claim 1 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,814,966. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7.2 Claims 18-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,531,128, in view of Andrulis et al., U.S. Patent No. 5654312.

Andrulis et al. teach that thalidomide is a TNF alpha inhibitor and can be administered therapeutically.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the patent is drawn to a method for treating a subject with glaucoma comprising the steps of administering a compound or composition containing an agent or molecule which antagonizes, inhibits, inactivates, reduces, suppresses, and/or limits the

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release, synthesis, or production of TNF- α from cells. Dependent claims of the patent are drawn to treatment with etanercept or anti-TNF- α antibody, while dependent claims in the instant application are drawn to treatment with thalidomide. It would have been prima facie obvious to treat glaucoma with thalidomide, since Andrulis et al. teach that thalidomide is a TNF alpha inhibitor and can be administered therapeutically.

7.3 Claims 18-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-8 of U.S. Patent No. 6,814,966, in view of Andrulis, U.S. Patent No. 5654312. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the patent is drawn to a method for treating a subject with glaucoma comprising the steps of administering a compound or composition containing an agent or molecule which antagonizes, inhibits, inactivates, reduces, suppresses, and/or limits the release, synthesis, or production of TNF- α from cells in the retina, wherein claim 1 of the instant application is drawn to a method for treating a subject with glaucoma comprising the steps of administering a compound or composition containing an agent or molecule which antagonizes, inhibits, inactivates, reduces, suppresses, and/or limits the release, synthesis, or production of TNF- α from cells. Dependent claims of the patent are drawn to treatment with anti-TNF- α antibodies, while dependent claims in the instant application are drawn to treatment with thalidomide. It would have been prima facie obvious to treat glaucoma with thalidomide, since Andrulis et al. teach that thalidomide is a TNF alpha inhibitor and can be administered therapeutically.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 22 are indefinite because claim 21 depends from itself, and claim 22 depends from claim 21.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nichol can be reached at (571) 272-0835.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

A handwritten signature in cursive script that reads "Eileen B. O'Hara".

EILEEN B. O'HARA
PRIMARY EXAMINER